UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/705,241	12/27/95	AMSTUTZ	5865-0009.31

EXAMINER: G

18N2/0807

KEMLINGER & ASSOCIATES
P O BOX 60850
PALO ALTO CA 94306

ART UNIT: 1811 | PAPER NUMBER: 2

DATE MAILED: 08/07/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ← days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ Notice to Comply.

Part II SUMMARY OF ACTION

1. ☒ Claims 1 — 17 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 11-17 are allowed.
4. ☒ Claims 1 — 10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing analgesia or treatment of pain, does not reasonably provide enablement for prevention of neuropathic pain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. There is no teaching or further guidance as to the prevention of neuropathic pain. When is the peptide of the invention administered? How is the prevention monitored or determined? There are no representative tests or data or other guidance demonstrating the prevention of pain. All test data set forth appear to be drawn to the inhibition of pain or treatment of pain or production of an analgesic

effect. In view of the unpredictability of peptide compounds which is well known in art, the lack of the proper and sufficient guidance in the instant specification and the lack of representative examples set forth, the instant claims lack enablement.

With respect to the adequacy of disclosure that a claimed genus possesses an asserted utility representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility. In re Oppenauer, 31 CCPA 1248, 143 F.2d 974, 62 USPQ 297; In re Cavallito et al., 48 CCPA 711, 282 F. 2d 357, 127 USPQ 202.

For a disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of a claim will possess the alleged utility. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

In view of the above, it is the Examiner's position that one skilled in the art could not make and/or use the invention without undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. § 102(e) as anticipated by or in the alternative under 35 U.S.C. §103(a) as being unpatentable over Justice et al. The reference teaches conotoxin peptides effective to produce analgesia. The reference further teaches a method of producing analgesia in a mammalian subject experiencing neuropathic pain. " The method includes administering to the subject an omega conopeptide which is effective (a) to inhibit electrically stimulated contraction of the guinea pig ileum and (b) to bind selectively and reversibly to omega conopeptide MVIIA binding sites present in neuronal tissue, where the activities in

these assays are within the activities of omega conopeptides MVIIA (SNX-111) and TVIA (SNX-185)." See column 3, lines 57-67 and column 4, lines 1-11.

The prior art is drawn to a method of preventing progression of neuropathic pain in a subject, comprising administering to the subject an N-type voltage-sensitive calcium channel blocking compound which is effective (a) to inhibit electrically stimulated contraction of the guinea pig ileum and (b) to bind selectively to omega conopeptide MVIIA binding sites present in neuronal tissue, as evidenced by the ability of the compounds to displace MVIIA from said site.

The difference in the prior art and the instant invention if there is one, is the interpretation of the "method of preventing the progression of neuropathic pain"as set forth in the instant claims.

The prior art methods and compounds teach the administration of an omega conopeptide which is an N-type calcium channel blocking compound, further the prior art teaches a compound which is effective (a) to inhibit electrically stimulated contraction of the guinea pig ileum and (b) to bind selectively to omega conopeptide MVIIA binding sites present in neuronal tissue, as evidenced by the ability of the compounds to displace MVIIA from said site. In view of the use of the same compounds as the prior art which produce the same activities as the instant

invention, the prior art anticipates or in the alternative renders obvious the instant invention methods. The only apparent difference is the preamble of the instant invention which is drawn to a "method of preventing the progression of neuropathic pain". There is no real showing that the method of prevention set forth is different from a method of inhibition of neuropathic pain in the absence of a showing of unexpected results.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 08/613400. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the method of producing analgesia by administration of an omega conopeptide through an epidural route of administration overlaps with the instant invention claims as set forth.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-17 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002. The examiner can normally be reached on Tuesday-Friday from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Avis M. Davenport

AVIS M. DAVENPORT
PRIMARY EXAMINER
GROUP 1800